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I hereby certify that this paper is being filed with Dianne Maggard of the United States Patent and Trademark Office by facsimile transmission on August 19, 2004 to facsimile telephone number (703) 308-6200.

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David W. Hibler

41,071

(Reg. No.)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant(s):	Turner, Jr. et al.	Group Art Unit:	1647
Application No.:	09/770,643	Appeal No.:	2004-1040
Filed:	01/26/2001	Examiner:	R. Landsman
Title:	Polynucleotides Encoding Human Neurexin-Like Proteins (As Previously Amended)	Atty. Docket No.:	LEX-0122-USA

RESPONSE TO ORDER UNDER 37 C.F.R. § 1.196(d) DATED JULY 19, 2004

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellants acknowledge the receipt of the Order Under 37 C.F.R. § 1.196(d) ("the Order") mailed on July 19, 2004, which has been carefully reviewed and studied. Appellants address the issues raised in the Order below.

A one month non-extendable time limit for response is set forth in the Order. The response is therefore timely filed, and Appellants believe no fees are due in connection with this response. However, the Commissioner is authorized to charge any required fees or credit any overpayment to Deposit Account No. 50-0892.

RESPONSE

The Board states that "(t)he Appeal Brief in this appeal includes essentially the same arguments that were made and rejected by the previous merits panel in Appeal No. 2004-0343", and thus, the Board "require Appellants to explain why we should again address the same line of argument in this case" (the Order at page 4, emphasis in original).

Appellants respectfully invite the Board to consider that the Appeal Brief in the present case describes two credible, specific, substantial, and well-established utilities that were not applicable, and thus not briefed, in Appeal No. 2004-0343. First, Appellants respectfully point-out that pages 4-11 of the present Appeal Brief describe, *inter alia*, evidence of record that clearly establishes that the present application and claims meet the administrative requisites outlined in Example 10 of the Revised Interim Utility Guidelines Training Materials. Unlike the Appeal Brief in Appeal No. 2004-0343, the present Appeal Brief describes: 1) Sequences sharing nearly 100% percent identity at the protein level over the entire length of the claimed sequence are present in the leading scientific repository for biological sequence data (GenBank); 2) That the identified sequences have been annotated by third party scientists *wholly unaffiliated with Appellants* as "Homo sapiens caspr5 protein" (GenBank accession numbers NM_130773 (see Exhibit A of the Appeal Brief) and AB077881 (see Exhibit B of the Appeal Brief)); 3) That it is well-known in the art that caspr proteins are distinct members of the neurexin superfamily (see Exhibit C of the Appeal Brief); 4) That the previously described caspr proteins (caspr 2, 3 and 4) share between 42% and 63% homology with each other (see Exhibits D-F of the Appeal Brief), but only 23% to 26% homology to neurexins 1, 2 and 3 (see Exhibits G-O of the Appeal Brief); and 5) That Appellants' sequence shares between 48% and 59% homology to other caspr proteins (see Exhibits P-R of the Appeal Brief) but only 24% to 26% homology to the neurexin proteins (see Exhibits S-U of the Appeal Brief). Given the scientific evidence of record, there can be no question that those skilled in the art would clearly believe that Appellants' sequence is a caspr protein, as opposed to "other members of the neurexin superfamily", as asserted by the Examiner. Therefore, Appellants point out in the Appeal Brief that the present case directly tracks Example 10 of the Revised Interim Utility Guidelines Training Materials (see Exhibit V of the Appeal Brief), which clearly establishes that a rejection under 35 U.S.C. § 101 as allegedly lacking a patentable utility and under 35 U.S.C. § 112, first paragraph as allegedly unusable by the skilled artisan due to the alleged lack of patentable utility is not proper when a full length sequence (such

as the presently claimed sequence) has a similarity score greater than 95% to a protein having a known function (such as the nearly 100% identity between the presently claimed sequence and the caspr 5 sequences, as discussed above). Thus, as set forth in the Appeal Brief, Appellants contend that the presently claimed sequence clearly meets the requirements of 35 U.S.C. § 101.

Second, Appellants respectfully point out that the present Appeal Brief details, from pages 11-15, yet another example of the utility of the present sequence. Specifically, the present nucleic acid sequences have utility in forensic analysis. The Appeal Brief details that the presently claimed sequence defines a coding single nucleotide polymorphism - specifically, a C/T polymorphism at position 812 of SEQ ID NO:1, which can lead to a serine or leucine residue at amino acid position 271 of SEQ ID NO:2. Appellants point out in the Appeal Brief that as such polymorphisms are the basis for forensic analysis, which is undoubtedly a "real world" utility, the presently claimed sequence clearly meets the requirements of 35 U.S.C. § 101.

The facts and evidence supporting the clear and legally valid utilities described above were neither applicable nor discussed in Appeal No. 2004-0343. While Appellants acknowledge that Appeal No. 2004-0343 dealt with some issues of utility set forth in the present Appeal Brief, Appellants respectfully request that the Board consider that the evidence and facts of record in the present Appeal merit, if not logically require, an outcome opposite from that reached by the Board in Appeal No. 2004-0343. The Board is thus requested to consider that the prior rejection of some of Appellants' assertions of utility should not end the present inquiry, for, as clearly set forth by the Federal Circuit, and set forth in the present Appeal Brief, Appellants need only make one credible assertion of utility to meet the requirements of 35 U.S.C. § 101 (*Raytheon v. Roper*, 220 USPQ 592 (Fed. Cir. 1983); *In re Gouilleb*, 140 USPQ 665 (CCPA 1964); *In re Malachowski*, 189 USPQ 432 (CCPA 1976); *Hoffman v. Klaus*, 9 USPQ2d 1657 (Bd. Pat. App. & Inter. 1988)). Furthermore, Appellants respectfully submit that all issues relating to patentable utility are required to be raised and contested in order to preserve such issues for appeal to the Federal Circuit, which has not yet determined the broader legality of the Patent Office's imposition of a distinct and more onerous standard of utility for biotechnology sequence inventions.

Therefore, given that a number of assertions of utility are set forth by Appellants in the present Appeal Brief that were not addressed by the previous merits panel in Appeal No. 2004-0343, Appellants respectfully request the Board to address all of the assertions of utility set forth by

Appellants in the Appeal Brief in the present case, and to overrule the rejections of claims 1-3 and 6-8 under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph.

Respectfully submitted,

August 19, 2004

Date



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Date: August 19, 2004

Phone:

Pages: 5 (including coversheet)

Re: Appeal No. 2004-1040
Application Serial Number: 09/770,643
Atty. Dkt. No. LEX-0122-USA

CC: File

Comments:

Please find attached a Response to the Order Under 37 C.F.R. § 1.196(d) in reference to the above-referenced appeal. Please contact me at the number shown above if there are any questions.